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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,982

06/15/2006

Robert C. Shipman

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7590

08/07/2008

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EXAMINER

POHNERT, STEVEN C

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

08/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,982	Applicant(s) SHIPMAN ET AL.	
	Examiner Steven C. Pohnert	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,50 and 78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49,50 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/25/2008 has been entered.

Claim status

This action is in response to papers filed 4/25/2008.

Claims 1-48, 51-77, 79-85 are canceled.

Claims 49 and 78 have been amended.

Claims 49, 50, and 78 are pending.

The objection to the claims has been withdrawn as the claims are canceled.

The written description rejection of claims 49, 50, and 78 are withdrawn due to the amendment and new written description guidelines.

The 112-2nd paragraph rejection of claims 49-50 has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

Maintained rejection

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Deneffe et al (WO02/46458, published June 13, 2002).

Claim 49 is drawn to an array containing two or more of the nucleic acids shown in SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44. The recitation, "of shown in" broadly encompasses any nucleic acid fragment, from a dinucleotide to the complete sequence of the recited SEQ ID NO.

With regards to claim 49, Deneffe teaches SEQ ID No 1-4 and 9-126. Deneffe thus anticipates the claims as he teaches two or more sequences shown in SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, and 44.

With regards to claim 50, Deneffe teaches of probes attached to a solid support. The solid support of Deneffe is a substrate with at least one target nucleic acid immobilized and thus a microarray. Deneffe thus anticipates claim 50.

Response to arguments

The response asserts that the claims have been amended to replace "as shown in" with "of", however the claim 49 has not been amended in such a manner. Thus the claims broadly encompass any nucleic acid sequence that can broadly be interpreted to be "shown in" the recited SEQ ID NO. This rejection can be overcome by amending claim 49 to recite "the nucleic acid sequences consisting of."

3. Claims 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796, issue December 12, 1995).

Claim 49 is drawn to an array containing two or more of the nucleic acids shown in SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44. The recitation of shown in broadly encompasses any nucleic acid fragment, from a dinucleotide to the complete sequence of the SEQ ID NO.

With regards to claim 49, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence that hybridizes Brennan thus anticipates the claims as he teaches two or more sequences of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or nucleic acid prepared by using amplification using primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135 or fragments that hybridize to one ABC transporter genes.

With regards to claim 50, Brennan teaches the array is a glass plate to which the oligonucleotides are immobilized (see column 7, lines 21-25). Brennan thus anticipates claim 50.

Response to arguments

The response asserts that the claims have been amended to replace "as shown in" with "of", however the claim 49 has not been amended in such a manner. Thus the claims broadly encompass any nucleic acid sequence that can broadly be interpreted to be "shown in" the recited SEQ ID NO. This rejection can be overcome by amending claim 49 to recite "the nucleic acid sequences consisting of."

New Grounds of Rejection

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 49, 50 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deneffe et al (WO02/46458, published June 13, 2002) in view of Dean et al (Journal of Lipid Research (2001) volume 42, pages 1007-1017); Monahan et al (WO2/071928 published 19 September 2002) (only relevant pages were provided due to length of disclosure); Schmitz (WO00/18912 PUBLISHED April 6, 2000); GenBank accession AC069137.6 GI:14589784 Published July 3, 2001); Boyd et al (WO01/62977 published August 21, 2001); Gen Bank Accession U63970.1 GI:1764161 (published Jan 7, 1997); Wan et al (WO2002/74979, published September 26, 2002) (only relevant pages were provided due to length of disclosure); Kruh et al (WO99/49735 published

Oct 7, 1999); GenBank Accession Z31010.1 GI:479155 (published May 11, 1995); Ota et al (EP1074617A2 published 07.02.2001) (only relevant pages were provided due to length of disclosure).

This rejection of claims 49 and 50 is drawn to the interpretation that the claims require sequences comprising SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44.

Denefle teaches characterization of new ABC genes will yield important transporter genes (see page 3, lines 27-29). Denefle teaches, "Thus, the probes according to the invention, immobilized on a support, may be ordered into matrices such as "DNA chips". Denefle thus teaches a microarray of ABC transporter genes.

Denefle does not teach probes consisting of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, and 44. Denefle does not suggest the combination of probes of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, and 44.

However, Dean et al teaches the ABC transporter family comprises 48 known ATP driven transporters, which have numerous important biological functions (see page 1007). Dean teaches the ABC family genes are known to play a role in the cell and mutations in the ABC gene transporter have been found in cystic fibrosis, neurological disease, retinal degeneration, cholesterol and bile transport defects, anemia, and drug response.

Monahan teaches sequence ABS76368 which comprises nucleotides of 3781 to 4570 are identical to SEQ ID NO 12.

Schmitz et al teaches AAZ94742 which comprises nucleotides 3082-3871 are identical to SEQ ID NO 15.

GenBank accession AC069137.6 GI:14589784 teaches nucleotides 93414 to 92662 comprising SEQ ID NO 21 of instant invention.

Boyd WO0162977 teaches GenBank accession AX282509.1 GI:16609639 nucleotides 21344 to 22003 which comprise SEQ ID NO of instant invention.

Gen Bank Accession U63970.1 GI:1764161 teaches nucleotides 4011-4820 which comprise the nucleotides of SEQ ID NO 23.

Wan teaches sequence ABZ35350 nucleotides 4566 to 5286 which comprises SEQ ID NO 24 of instant invention.

Kruh et al teach sequence AAZ30078 nucleotides 3336 to 4129 which comprises SEQ ID NO 25 of instant invention.

Kruh et al teach sequence AAZ30079 nucleotides 4964 to 5069 which comprises SEQ ID NO 26 of instant invention.

GenBank Accession Z31010.1 GI:479155 teaches nucleotides 1280 to 1767 which comprise SEQ ID NO 35 of instant invention.

Ota et al (EP1074617A2 published 07.02.2001) teaches SEQ ID NO 12961 nucleotides 1387 to 2010 which comprise SEQ ID NO 44 of instant invention.

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the sequences taught by Monahan et al, Schmitz, GenBank accession AC069137.6 GI:14589784, Boyd et al, Gen Bank Accession U63970.1 GI:1764161, Wan et al, Kruh et al, GenBank Accession Z31010.1 GI:479155, and Ota et al which comprise SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 in the array taught by Deneffe. Designing probes, which are equivalents

to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes. Moreover there are many internet web sites that provide free downloadable software to aid in the selection of probes drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes. As discussed above, the ordinary artisan would be motivated to have designed and tested new probes to obtain additional oligonucleotides that function to detect specific SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 and identify oligonucleotides with improved properties. The ordinary artisan would have a reasonable expectation of success of obtaining additional probes from the known sequences. Thus, for the reasons provided above, the ordinary artisan would have designed additional probes using the teachings in the art at the time the invention was made. The claimed SEQ ID NOs are obvious over the cited prior art, absent secondary considerations. The artisan would be motivated to combine the nucleic acid sequences taught by Monahan et al, Schmitz, GenBank accession AC069137.6 GI:14589784, Boyd et al, Gen Bank Accession U63970.1 GI:1764161, Wan et al, Kruh et al, GenBank Accession Z31010.1 GI:479155, and Ota et al because Dean teaches ABC gene transporters are important and known to play a role in human diseases including cystic fibrosis, neurological disease, retinal degeneration, cholesterol and bile transport defects, anemia, and drug response, thus determining expression would allow better diagnosis. The substitution or addition of the sequences taught by Monahan et al, Schmitz, GenBank accession

AC069137.6 GI: 14589784, Boyd et al, Gen Bank Accession U63970.1 GI: 1764161, Wan et al, Kruh et al, GenBank Accession Z31010.1 GI: 479155, and Ota et al in the arrays taught by Deneffe would produce a microarray with probes equivalent to the recited SEQ ID NO by replacing or adding known ABC transporter gene sequences for another. The artisan would have a reasonable expectation of success as methods of synthesizing nucleic acids and making arrays as well as the sequences of ABC transporter genes were known at the time of the invention.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Sarae Bausch/
Primary Examiner, Art Unit 1634